Opening Statement
Chairman Fred Upton
Subcommittee on Health Hearing
Wednesday, February 15, 2012

(As Prepared for Delivery)

Encouraging a well-run FDA and promoting innovation has been a focal point of the Energy and Commerce Committee. During this Congress, the committee has held three hearings and hosted a jobs forum where we heard from entrepreneurs, inventors, and small business owners in the medical device industry. Directly and indirectly, these businesses employ about 2 million people. In my home state of Michigan, the medical device industry—led by great American companies such as Stryker—employs approximately 9,000 people. However, these companies told the committee that the lack of predictability at FDA is forcing American companies to move jobs to Europe.

The lack of predictability is also harming American patients. Last July, Marti Conger testified before our committee that she had to deplete her life savings and travel to England to benefit from a device developed and manufactured by a company located forty miles from her house in California.

To address these concerns, members of the committee and a medical device champion on the Ways and Means Committee, Congressman Paulsen, introduced legislation designed to bring predictability, consistency, and transparency to FDA regulation.

Ultimately, the goal of these reforms is to save patients, promote innovation, and create jobs without sacrificing quality or safety. A goal that, I believe, is bipartisan and consistent with the goal of Commissioner Hamburg and the FDA.

Finally, I understand that FDA and the device industry have come to a proposed user fee agreement. That is welcome news, but, in order for the committee to complete its work on the user fees on schedule, we need to get the proposed user fee agreement as soon as possible. I ask FDA and the administration to do all that they can to make that happen.